K120013

SYBRON DENTAL SPECIALTIES

MAY 22 2012

**510(k) Summary**

Submitter:

Sybron Dental Specialties, Inc.
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Wendy Garman - Contact Person

Date Summary Prepared: April 2012

- Trade name – *TempSpan Clear Matrix*
- Common name – Impression Material
- Classification name – Material, Impression (21 CFR 872.3660, ELW)

Devices for Which Substantial Equivalence is Claimed:

- Memosil 2, Class II, K913537 , Product Code ELW, Heraeus Kulzer
- Elite Glass, Class II, K073005, ELW, Zhermack S.P.A.
- Correct VPS, Class II, K914178, Product Code ELW, Pentron Clinical

Summary

Device Description

*TempSpan Clear Matrix* Material is a clear preoperative impression material that will reproduce the finest detail resulting in extremely accurate provisional restorations. Use as the preliminary impression material for intraoral and extra-oral polymerization of dual-cure provisional materials. Light curing dual-cure provisional materials may eliminate or drastically reduce the oxygen-inhibited smear layer.

*TempSpan Clear Matrix* Material is a medium viscosity vinyl polysiloxane material. It is packaged in a 50ml auto-mix cartridge, with an oral set time of 2 minutes. *TempSpan Clear Matrix* Material enables provisional restorations fabricated with dual cure materials to be light cured intra-orally and extra-orally. This process shortens the provisional procedure, minimizing chair time and patient discomfort. Additional

features include: clear formula for intra-oral light curing, auto-mix delivery, and a quick set time with a working time of 1 minute and an oral set time of 2 minutes.

When used in a clear impression tray, *TempSpan Clear Matrix* can be used to create light cured temporary restorations inside a patient's mouth. To begin the process, the clinician will select a rigid, clear plastic tray and use *TempSpan Clear Matrix* to take an impression of the patient's current state. The impression is set aside while the clinician prepares the tooth for a crown, bridge, etc. When it is time to make the temporary restoration, the impression made using *TempSpan Clear Matrix* is used to form the temporary restoration. This is completed through the following procedure:

1) The temporary restoration material is applied directly into the *TempSpan Clear Matrix* impression.
2) The impression and temporary restoration material are placed in the patient's mouth and the material is light-cured through the clear impression tray.
3) Once the clear tray is removed, the temporary restoration remains attached to the patient's prepared tooth.

The clinician also has the option of using *TempSpan Clear Matrix* with the more traditional method of creating and cementing a temporary restoration. In this option, the clear impression is removed and the selected temporary restorative material is left to fully cure outside of the mouth. The clinician would then remove the temporary restoration from the clear impression and cement it onto the prepared tooth using a temporary cement.

Intended use of the Device

*TempSpan Clear Matrix is indicated for:*

- Use as a clear template for intra oral polymerization of light activated materials to create temporary restorations.
- Use as a general impression material for monophase impression techniques.

Technological Characteristics Compared to Predicate

*TempSpan Clear Matrix* is substantially equivalent to other legally marketed devices in the United States. *TempSpan Clear Matrix* functions in a manner similar to Memosil 2, which is currently marketed by Heraeus Kulzer, Elite Glass which is currently marketed by Zhermack S.P.A., and Correct VPS which is currently marketed by Pentron Clinical.

Non-Clinical Performance Data

Biocompatibility studies were completed, which demonstrate that the material is safe for its intended use. *TempSpan Clear Matrix* was tested through the ISO Intramuscular Injection Test and the ISO L929 MEM Elution Test, and was found to be a negligible irritant and non-cytotoxic.

The 510(k) submission also includes data from bench testing used to evaluate performance characteristics of *TempSpan Clear Matrix* compared to the predicate devices, Memosil 2 currently marketed by Heraeus Kulzer, Elite Glass currently marketed by Zhermack S.P.A., and Correct VPS currently marketed by Pentron Clinical. The characteristics evaluated include Work Time, Oral Set Time and Shore A Hardness.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *TempSpan Clear Matrix* is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pentron Clinical
Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867

MAY 2 2 2012

Re: K120013
Trade/Device Name: TempSpan Clear Matrix
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 2, 2012
Received: May 3, 2012

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K120013

**Device Name:** *TempSpan Clear Matrix*

**Indications For Use:**

*TempSpan Clear Matrix is indicated for:*

- Use as a clear template for intra oral polymerization of light activated materials to create temporary restorations.
- Use as a general impression material for monophase impression techniques.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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